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APPLICATION NO.	FILING DATE	FIRST NAMED INVENTOR	ATTORNEY DOCKET NO.	CONFIRMATION NO.
09/359,426	07/22/1999	ALLAN WILLIAM CRIPPS	064727.0105	2788

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BAKER & BOTTS LLP
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EXAMINER

DEVI, SARVAMANGALA J N

ART UNIT	PAPER NUMBER
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1645

DATE MAILED: 02/18/2004

Please find below and/or attached an Office communication concerning this application or proceeding.

Office Action Summary

Application No.

09/359,426

Applicant(s)

CRIPPS ET AL.

Examiner

S. Devi, Ph.D.

Art Unit

1645

-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --

Period for Reply

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE 3 MONTH(S) FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If the period for reply specified above is less than thirty (30) days, a reply within the statutory minimum of thirty (30) days will be considered timely.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133). Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

Status

- 1) ☒ Responsive to communication(s) filed on 21 November 2003.
- 2a) ☐ This action is FINAL. 2b) ☒ This action is non-final.
- 3) ☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

Disposition of Claims

- 4) ☒ Claim(s) 1, 7, 9, 18, 20-22, 24-27, 36 and 37 is/are pending in the application.
- 4a) Of the above claim(s) _____ is/are withdrawn from consideration.
- 5) ☒ Claim(s) 1, 7, 21, 24 and 26 is/are allowed.
- 6) ☒ Claim(s) 9, 18, 20, 22, 25, 27, 36 and 37 is/are rejected.
- 7) ☐ Claim(s) _____ is/are objected to.
- 8) ☐ Claim(s) _____ are subject to restriction and/or election requirement.

Application Papers

- 9) ☐ The specification is objected to by the Examiner.
- 10) ☐ The drawing(s) filed on _____ is/are: a) ☐ accepted or b) ☐ objected to by the Examiner.
Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).
Replacement drawing sheet(s) including the correction is required if the drawing(s) is objected to. See 37 CFR 1.121(d).
- 11) ☐ The oath or declaration is objected to by the Examiner. Note the attached Office Action or form PTO-152.

Priority under 35 U.S.C. § 119

- 12) ☒ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).
- a) ☒ All b) ☐ Some * c) ☐ None of:
1. ☒ Certified copies of the priority documents have been received.
2. ☐ Certified copies of the priority documents have been received in Application No. _____.
3. ☐ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).
- * See the attached detailed Office action for a list of the certified copies not received.

Attachment(s)

- 1) ☐ Notice of References Cited (PTO-892)
- 2) ☐ Notice of Draftsperson's Patent Drawing Review (PTO-948)
- 3) ☒ Information Disclosure Statement(s) (PTO-1449 or PTO/SB/08)
Paper No(s)/Mail Date 022004.
- 4) ☐ Interview Summary (PTO-413)
Paper No(s)/Mail Date. _____.
- 5) ☐ Notice of Informal Patent Application (PTO-152)
- 6) ☐ Other: _____.

DETAILED ACTION

Request for Continued Examination

1) A request for continued examination under 37 C.F.R 1.114, including the fee set forth in 37 C.F.R 1.17(e), was filed in this application after final rejection. Since this application is eligible for continued examination under 37 C.F.R 1.114, and the fee set forth in 37 C.F.R 1.17(e) has been timely paid, the finality of the previous Office action has been withdrawn pursuant to 37 C.F.R 1.114. Applicants' submission filed on 11/21/03 has been entered.

Applicants' Amendments

2) Acknowledgment is made of Applicants' amendments filed 09/22/03 and 11/21/03 in response to the final Office Action mailed 03/20/03. With this, Applicants have amended the specification.

Status of Claims

3) Claims 1, 9, 20 and 21 have been amended via the amendment filed 09/22/03.
Claims 4, 8 and 19 have been canceled via the amendment filed 09/22/03.
New claim 37 has been added via the amendment filed 09/22/03.
Claims 1, 7, 9, 18, 20-22, 24-27, 36 and 37 are under examination.

Information Disclosure Statement

4) Acknowledgment is made Applicants' Information Disclosure Statement filed 09/22/03. The information referred to therein has been considered and a signed copy is attached to this Office Action.

Prior Citation of Title 35 Sections

5) The text of those sections of Title 35 U.S. Code not included in this action can be found in a prior Office Action.

Prior Citation of References

6) The references cited or used as prior art in support of one or more rejections in the instant Office Action and not included on an attached form PTO-892 or form PTO-1449 have been previously cited and made of record.

Objection(s) Moot

7) The objection to claim 4 in paragraph 34 of the Office Action mailed 03/20/03, as being improperly dependent is moot in light of Applicants' cancellation of the claim.

Rejection(s) Moot

8) The rejection of claim 4 made in paragraph 28 of the Office Action mailed 03/20/03 under 35 U.S.C. § 101 as being directed to a non-statutory subject matter, is moot in light of Applicants' cancellation of the claim.

- 9) The rejection of claims 4, 8 and 19 made in paragraph 29 of the Office Action mailed 03/20/03 under 35 U.S.C § 112, first paragraph, as containing new subject matter, is moot in light of Applicants' cancellation of the claims.
- 10) The rejection of claims 4 and 8 made in paragraph 30(c) of the Office Action mailed 03/20/0335 under U.S.C § 112, second paragraph, as being indefinite, is moot in light of Applicants' cancellation of the claims.
- 11) The rejection of claims 4 and 8 made in paragraph 32 of the Office Action mailed 03/20/03 under 35 U.S.C § 102(e) as being anticipated by Green *et al.* (US 6,100,380, filed 06/07/1995) as evidenced by Foster *et al.* (US 6,436,391, filed 01/31/1997), is moot in light of Applicants' cancellation of the claims.
- 12) The rejection of claims 4, 8 and 19 made in paragraph 33 of the Office Action mailed 03/20/03 under 35 U.S.C § 103(a) as being unpatentable over Green *et al.* (US 6,100,380, filed 06/07/1995), is moot in light of Applicants' cancellation of the claims.

Rejection(s) Withdrawn

- 13) The rejection of claims 1, 7, 9, 18, 20-22 and 24-27 made in paragraph 29 of the Office Action mailed 03/20/03 under 35 U.S.C § 112, first paragraph, as containing new subject matter, is withdrawn in light of Applicants' amendments to the base claim(s).
- 14) The rejection of claim 1 made in paragraph 30(a) of the Office Action mailed 03/20/0335 U.S.C § 112, second paragraph, as being indefinite, is withdrawn in light of Applicants' amendments to the claim.
- 15) The rejection of claim 9 made in paragraph 30(b) of the Office Action mailed 03/20/0335 U.S.C § 112, second paragraph, as being indefinite, is withdrawn in light of Applicants' amendments to the claim.
- 16) The rejection of claims 21, 22 and 24-27 made in paragraph 30(c) of the Office Action mailed 03/20/0335 under U.S.C § 112, second paragraph, as being indefinite, is withdrawn in light of Applicants' amendments to the base claim(s).
- 17) The rejection of claims 1, 9, 21, 22 and 24-27 made in paragraph 32 of the Office Action mailed 03/20/03 under 35 U.S.C § 102(e) as being anticipated by Green *et al.* (US 6,100,380, filed 06/07/1995) as evidenced by Foster *et al.* (US 6,436,391, filed 01/31/1997), is withdrawn in light of Applicants' amendments to the claims and/or the base claim(s).
- 18) The rejection of claims 1, 9, 20 and 36 made in paragraph 33 of the Office Action mailed 03/20/03 under 35 U.S.C § 103(a) as being unpatentable over Green *et al.* (US 6,100,380, filed 06/07/1995), is withdrawn in light of Applicants' amendments to the claims and/or the base claim(s).

Rejection(s) under 35 U.S.C. 112, First Paragraph

19) Claims 9, 22, 25, 27 and 36 are rejected under 35 U.S.C § 112, first paragraph, as containing subject matter which was not described in the specification in such a way as to reasonably convey to one skilled in the relevant art that the inventor(s), at the time the application was filed, had possession of the claimed invention. This is a new matter rejection.

Claim 9, as amended, includes the new limitations: 'a second' *P. aeruginosa* protein or 'a fragment of said second protein'. Applicants point to page 2, lines 25-28 and lines 34-36 as providing descriptive support for these limitations. However, this part of the specification does not provide descriptive support for any 'second' *P. aeruginosa* protein or a fragment of said 'second protein'. Therefore, the above-identified limitation in the claim(s) is considered to be new matter. New matter includes not only the addition of wholly unsupported subject matter but also, adding specific percentages or compounds after a broader original disclosure, or even omission of a step from a method. *In re Rasmussen*, 650 F2d 1212 (CCPA, 1981). See M.P.E.P. 608.04 to 608.04(c).

Applicants are invited to point to the descriptive support in specific part(s) of the disclosure, as originally filed, for the limitations identified above, or to remove the new matter from the claims and/or the base claim(s). It is suggested that Applicants replace the recitation with --an additional *P. aeruginosa* protein or an antigenic fragment of said additional protein--.

Rejection(s) under 35 U.S.C. 112, Second Paragraph

20) Claims 9, 18, 20, 22, 25, 27, 36 and 37 are rejected under 35 U.S.C § 112, second paragraph, as being indefinite, for failing to particularly point out and distinctly claim the subject matter which Applicants regard as the invention.

(a) Claims 18, 20 and 36 are vague and indefinite in the recitation 'diagnosing *P. aeruginosa*', because it is unclear what is encompassed in this limitation. It is not clear how a kit can be used for diagnosing a bacterium, such as, *P. aeruginosa*, or what is precisely involved in the process of 'diagnosing *P. aeruginosa*'. Usually what is 'diagnosed' using a kit is a disease, an infection, or a clinical condition caused by a microbial pathogen, but not a bacterial pathogen itself.

(b) Claim 9 is vague and indefinite in the recitation 'fragment of said second protein', because it is unclear what is encompassed in this limitation. What constitutes a 'fragment', and how much of the second protein's original structure has to be retained such that the resulting product can be considered as a 'fragment' is not clear. The metes and bounds of the structure encompassed in the limitation 'fragment' are indeterminate.

(c) In lines 3 and 4 of claim 37, in order to distinctly claim the subject matter of the invention,

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it is suggested that Applicants replace the limitation 'said fragment comprises an N-terminal amino acid sequence of' with --said antigenic fragment comprises the N-terminal amino acid sequence of--.

(d) Claims 22, 25, 27 and 36, which depend directly or indirectly from claim 9, are also rejected as being indefinite because of the indefiniteness or vagueness identified above in the base claim.

Remarks

21) Claims 9, 18, 20, 22, 25, 27, 36 and 37 stand rejected. Claims 1, 7, 21, 24 and 26 are allowable.

22) Papers related to this application may be submitted to Group 1600, AU 1645 by facsimile transmission. Papers should be transmitted via the PTO Fax Center, which receives transmissions 24 hours a day and 7 days a week. The transmission of such papers by facsimile must conform with the notice published in the Official Gazette, 1096 OG 30, November 15, 1989. The RightFax number for submission of before-final amendments is (703) 872-9306. The RightFax number for submission of after-final amendments is (703) 872-9307.

23) Any inquiry concerning this communication or earlier communications from the Examiner should be directed to S. Devi, Ph.D., whose telephone number is (571) 272-0854. A message may be left on the Examiner's voice mail system. The Examiner can normally be reached on Monday to Friday from 7.15 a.m. to 4.15 p.m. except one day each bi-week, which would be disclosed on the Examiner's voice mail system.

If attempts to reach the Examiner by telephone are unsuccessful, the Examiner's supervisor, Lynette Smith, can be reached on (571) 272-0864.

Any inquiry of a general nature or relating to the status of this application or proceeding should be directed to the Group receptionist whose telephone number is (703) 308-0196.

February, 2004


S. DEVI, PH.D.
PRIMARY EXAMINER